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UNIVERSITY OF WASHINGTON
CONSENT FORM**A prospective, controlled study of rehabilitation of anomia in aphasia**

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Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

If you decide you want to be in the study and sign this consent form, it is possible that based on the tests we do today we may find out the study is not a good fit for you. If this happens we will let you know, and you will not be able to participate in the study.

PURPOSE OF THE STUDY

The purpose of this study is to give speech therapy to individuals who have suffered a stroke and have difficulty speaking. This condition is called aphasia. This study will compare two treatments for aphasia. This study has been funded by a grant from VA Rehabilitation Research and Development office (RR&D). There will be 80 individuals with aphasia who will participate in this study.

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STUDY PROCEDURES

If you participate in this study, the following 5 steps will take place.

Step 1: Screen: If you are signing this consent form, you have already gone through Step 1. You have been asked several questions about your medical history. This was an initial screening to see if you met basic criteria for the study. You were asked to provide information regarding where you received medical care following your stroke. We have a waiver that allowed us to view your brain CT or MRI to confirm the left hemisphere stroke. You passed the initial screen and the CT/MRI screen, so your next step is Step 2.

Step 2: Randomization: You will be randomized (like a flip of a coin) to one of two treatment groups, Group A or Group B.

- Group A: phonological (treatment based in sounds)
- Group B: semantic (treatment based in words)

Step 3: Pre-treatment testing: You will meet with a speech language pathologist 4-5 times over the course of 1 week to receive pen/paper aphasia testing for a total of 10-15 hours. You will be video and audio recorded.

Step 4: Treatment phase: You will receive speech therapy for 60 total hours (1 hour sessions 2 times/day, 5 days/week for 6 weeks).

- **Group A:** phonological treatment is training individual sounds (consonants and vowels) and sound sequences (strings of consonants and vowels in 1-syllable, 2-syllable and 3-syllable words). Using 'talk therapy,' the therapist will teach you these sounds and sequences through visual (looking in a mirror), auditory (hearing the sounds), tactile-kinesthetic (feeling the sounds in the mouth) and speech motor (saying the sounds).
- **Group B:** semantic treatment is training whole words (e.g. nouns). Using 'talk therapy' the therapist will teach you nouns by showing you a picture (e.g. hammer) and asking you a series of questions about that noun (e.g. what do you do with it?, where do you store it in your home?, show me how you hold it, etc.). You will then be asked to name that picture (e.g. hammer). After naming the therapist will show you a new picture and repeat the same procedures.

Step 5: Post-treatment testing:

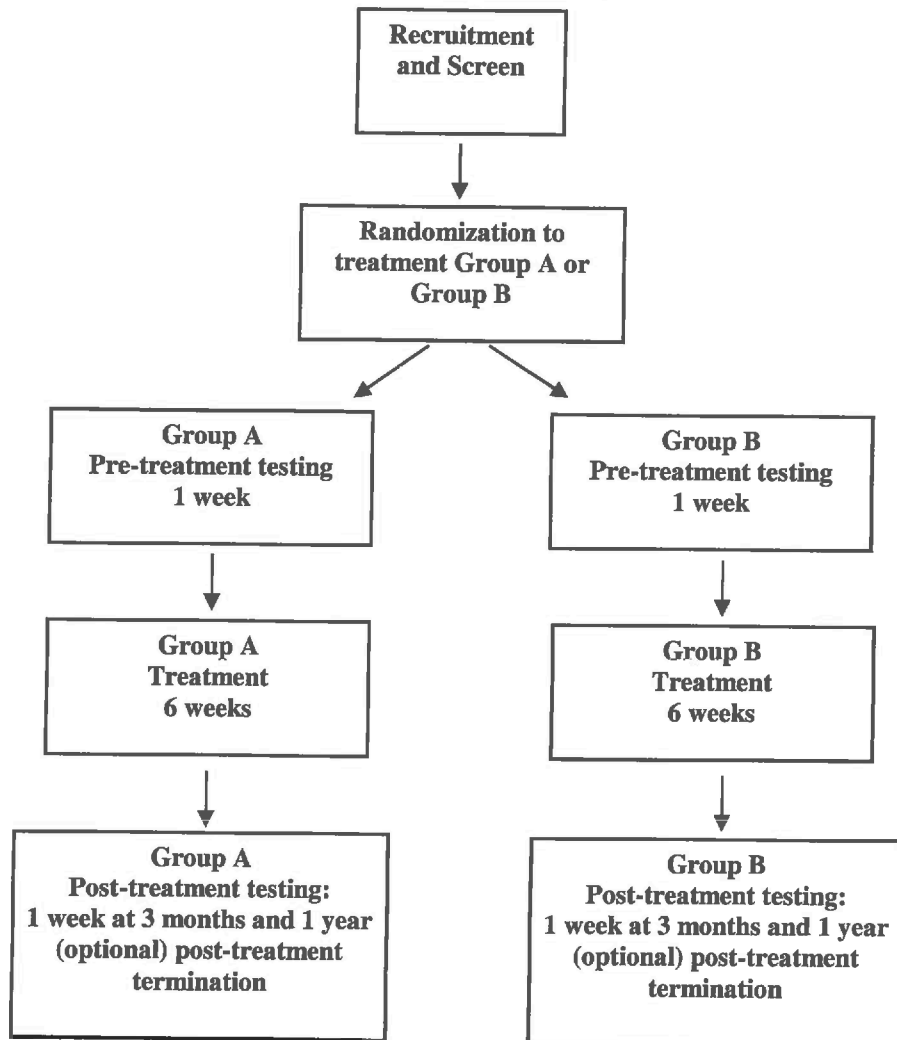
- Immediately following treatment and again three months later, you will meet with a speech language pathologist to receive the same pen/paper aphasia tests you received in Step 3. You will meet with the speech therapist 4-5 times over the course of 1 week for immediate and three month testing. They will be video and audio recorded.
- You have the option of returning 1 year from the end of treatment for another post-treatment testing session. You will meet with a speech

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language pathologist to receive the same pen/paper aphasia tests you received in Step 3. You will meet with the speech therapist 2-3 times over the course of one week for one year testing. They will be video and audio recorded.



RISKS, STRESS, OR DISCOMFORT

The only anticipated discomfort with this research study may be fatigue. In the event of fatigue, you may take a break from therapy.

The only anticipated inconvenience with this research study may be the intensive schedule of treatment. The therapist can come to your home if that will aid in travel.

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3 of 5

There is the potential of breach of confidentiality. Measures will be taken to ensure confidentiality, such as storing the information on a secure computer in a locked laboratory, password protecting the computer and password protecting the spreadsheet that contains the information. We will be sending audio and/or video recordings to a researcher at Portland State University, and we will ensure proper and safe transmission of your data to this researcher. Should there be a breach of confidentiality, you will be notified immediately.

Audio and video recordings will be kept indefinitely. If you sign the consent below the recordings may be used in presentations for educational purposes. You will be given an opportunity to review the recordings and delete any portions.

ALTERNATIVES TO TAKING PART IN THIS STUDY

The alternative to obtaining speech therapy through this study is to obtain it somewhere else. If you want to obtain speech therapy outside of the study you will need to check with your provider to find out what specific treatments are available to you through your provider. If you do not want to take part in this study, tell the Principal Investigator or her assistant and *do not sign* this Informed Consent Form. You are free to refuse to be in the study, and your refusal will not influence current or future health care you receive at this institution. Current standards of care will be followed whether you take part in this study or not.

BENEFITS OF THE STUDY

One potential benefit of receiving 60 hours of speech therapy is the ability to speak better.

SOURCE OF FUNDING

The study team and the University of Washington are receiving financial support from the Department of Veterans Affairs.

CONFIDENTIALITY OF RESEARCH INFORMATION

We will keep the link between your name and the code in a separate, secured location until 5 years after the end of study completion. Then we will destroy the link.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

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OTHER INFORMATION

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

For complete participation in the study you will receive \$300. By "complete" we mean after you complete the 3 month testing session. If you do not complete the entire study, you will be paid a pro-rated amount based on the amount of time you participated. You will be asked to provide your name, address and social security number in order to receive payment.

The only cost to you will be travel to the University of Washington or the VAPSMC.

Printed name of study staff obtaining consent	Signature	Date
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Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

Education

I give my permission for the researchers to use the audio and/or video recordings of my talking for education purposes in the future:

☐ No ☐ Yes If Yes, please initial here: _____ Date: _____

Printed name of subject	Signature of subject	Date
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Copies to: Researcher
 Subject

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5 of 5